Section 6

510(k) Summary of Safety and Effectiveness Information

5 Fr Dual Lumen Groshong®NXT PICC Catheter

6.1 Submitter Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 5439
Fax Number:	(801) 595-4903
Contact Person:	Peggy Keiffer
Date of Preparation:	September 26, 2002

6.2 Device Name

Device Name:	5 Fr Dual Lumen Groshong®NXT PICC Catheter
Trade Name:	5 Fr Dual Lumen Groshong®NXT PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Class II, 80 LJS – Long Term Intravascular Catheter
Classification Panel:	General Hospital

6.3 Predicate Device(s):

Device Name:	5 Fr Dual Lumen Groshong® PICC Catheter 3.0 Fr Groshong® PICC Procedure Tray
Trade Name:	Groshong®PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Class II, 80 LJS – Long Term Intravascular Catheter
Classification Panel:	General Hospital
Premarket Notification:	K904558, concurrence date February 11, 1991 K926331, concurrence date March 11, 1994

6.4 Device Description

The 5 Fr Dual Lumen silicone Groshong® NXT PICC Catheters feature a reverse-taper catheter design. They are 45 or 55 cm in length. The catheters have two equal-sized lumens and a closed, rounded, atraumatic, radiopaque, distal tip with the 3-position, pressure-sensitive Groshong® valve in each lumen. Valves are staggered for simultaneous infusion of incompatible solutions and/or aspiration of blood samples.

The proximal end of the catheter has a bifurcation with integral Statlock compatible suture wings. There are red and white plastic luer lock connectors on the extension legs. Extension legs are insert molded into the proximal end of the bifurcation. Catheters are provided sterile with a preloaded hydrophilic stiffening stylet.

6.5 Intended Use

The 5 Fr Dual Lumen Groshong® NXT PICC Catheter is designed for use in short term or long term intravenous therapy and any other therapies requiring long term central venous access (e.g. blood sampling). It is used for administration of hyperalimentation, chemotherapy and other I.V. fluids. The dual lumen feature permits simultaneous infusion of incompatible solutions and/or aspiration of blood samples. Refer to the appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information.

This is the same basic intended use as previously cleared for the 5 Fr Groshong® PICC Catheter, K904558, and the 3.0 Fr Groshong® PICC Procedure Tray.

6.5 Technological Characteristics Summary

New device is compared to Marketed Device

Yes.

Does the new device have the same indication statement?

Yes. However, there are minor modifications to the indication verbiage.

Does the new device have the same technological characteristics, e.g. design, material, etc.?

Not in all regards. The basic fundamental scientific technology of the catheter has not changed. However, the Groshong® NXT PICC has some minor differences from the predicate 5 Fr DL Groshong® PICC.

Could the new characteristics affect safety or effectiveness?

Yes. The new characteristics could affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. Design performance is in compliance with the FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/ 95.*

Biocompatibility of materials are in compliance with the requirements of *ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing*, and the FDA-Modified ISO 10993 Test Profile for externally communicating, blood-contacting, long-term devices.

Are performance data available to assess effects of new characteristics?

Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards.

Do performance data demonstrate equivalence?

Yes. Performance data gathered in design verification testing demonstrated that the Groshong® NXT PICC is substantially equivalent to the predicate 5 Fr DL Groshong® PICC (design).

6.6 Nonclinical Performance Testing

Testing was performed using the *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95* included assessments of:

Dimensions
Priming Volume
Flow Rate
Tensile, Elongation and Stiffness (Modulus) of Catheter Shaft
Tensile, Elongation and Stiffness (Modulus) of Extension Leg Tubing
Tensile:
- Extension Leg to Connector Tensile
- Extension Leg to Bifurcation Tensile
- Catheter Shaft to Bifurcation Tensile

Catheter Tip Tensile
Assembly Leak (Leak at Hub)
Catheter Burst:
- Assembly
- Extension Leg tubing

Catheter Collapse
Catheter Flexural Fatigue Tolerance (Cyclic Flexure)

Additional non-guidance testing performed:
Creep (Static)
Radiopacity
Valve Function
Stylet Drag

Guidance testing not performed:
Biocompatibility. No new materials were used

6.8 Conclusion

The 5 Fr DL Groshong® NXT PICC is substantially equivalent in design and intended use to the predicate device 5 Fr DL Groshong® PICC, K904558, cleared February 11, 1991 and has the same indication for use as the 3.0 Fr Groshong® PICC Procedure Tray, K926331, cleared March 11, 1994.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2002

Ms. Peggy Keiffer
Senior Regulatory Affairs Manager
C.R. Bard, Incorporated
Bard Access Systems, Incorporated
5425 W. Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K023374
Trade/Device Name: 5 Fr Dual Lumen Groshong® NXT PICC Catheter
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: October 3, 2002
Received: October 8, 2002

Dear Ms. Keiffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1-B

5 Fr Dual Lumen Groshong® NXT PICC Catheter 510(k)

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Senior Regulatory Affairs Manager of Bard Access Systems, that this notification [510(k)] for the following devices, 5 Fr Dual Lumen Groshong® NXT PICC Catheter, are indicated for the following:

The Groshong® NXT PICC provides short (less than 30 days) or long (greater than 30 days) term peripheral access to the central venous system for intravenous therapy or blood sampling.

Typed Name: Peggy Keiffer
Senior Regulatory Affairs Manager

Date: 10.4.02

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number K023374

Division Sign-Off
Office of Device Evaluation

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023374

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